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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,799	01/04/2002	J. Bruce Pitner	P-5504	9195
26253	7590	11/09/2004	EXAMINER	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			TELLER, ROY R	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,799

Applicant(s)

PITNER ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment, received 8/18/04, in which applicant amended claims 2, 6, 7, and 9.

Claims 1-13 are pending.

Claim Rejections - 35 USC § 112

Claims 1-13 stand rejected under 35 U.S.C. 112, first paragraph for the reasons of record.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the Examiner acknowledges that representative examples of the claimed genus of mutant binding proteins are enabled and no undue experimentation is needed to practice the instant invention.

With respect to the elected invention, Applicants have reasonably demonstrated that for a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149 , or a cysteine at position 213 results in signal-enhanced glucose detection as evidenced by figure 1 and figure 8 of the instant application. However, the claims broadly encompass a group of amino acid substitutions for a mutated glucose binding protein which are clearly beyond the scope of the instant disclosure.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable

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expectation of success, other than using a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149 , or a cysteine at position 213 results in signal-enhanced glucose detection as evidenced by figure 1 and figure 8 of the instant application.

Claim Rejections - 35 USC § 102

Claims 1-13 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Lakawicz (USPN 6,197,534) or by Hellinga (USPN 6,277,627) for the reasons of record.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the cited references do not teach or suggest the combination of a mutated protein and sensor surface.

Each of the cited references teach a sensor comprising a modified glucose binding protein (see '534 patent, i.e., for example, claims 30, 32, 33, 34, 35, 37 38, and 40, columns 15 and 16 and '627 patent, i.e., for example, claim 1, column 11). Further, Lakawicz et al. expressly teach the protein is modified by substituting at least one cysteine residue (see, i.e., for example, claims 37 and 38, columns 15 and 16). Lakawicz discloses polymeric layers containing labeled glucose/galactose binding protein (see, i.e., for example, column 11, lines 53-54).

Conclusion

All claims are rejected.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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11/5/04

RT

A handwritten signature in black ink, appearing to read 'CR Tate', with a stylized flourish at the end.

CHRISTOPHER R. TATE
PRIMARY EXAMINER